



UNITED STATES PATENT AND TRADEMARK OFFICE

SEP 14 2006

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

Steven P. O'Connor
Finnegan Henderson Farabow Garrett & Dunner LLP
901 New York Ave., NW
Washington DC 20001-4413

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,868,112

Dear Mr. O'Connor :

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,868,112 for a period of 1,258 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: <http://www.fda.gov/opacom/morechoices/fdaforms/default.html> (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at mary.till@uspto.gov.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD-7
5600 Fishers Lane (Rockwall II Rm 1101)
Rockville, MD 20857

RE: ReFacto® (novel procoagulant
proteins)
FDA Docket No.: 01E-0097

Attention: Beverly Friedman

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 4,868,112
(45) ISSUED : September 19, 1989
(75) INVENTOR : John J. Toole, Jr.
(73) PATENT OWNER : Genetics Institute LLC
(95) PRODUCT : ReFacto® (novel procoagulant proteins)

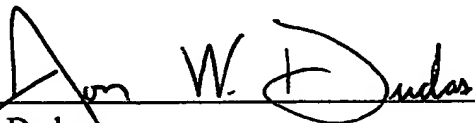
This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 4,868,112 based upon the regulatory review of the product ReFacto® (novel procoagulant proteins) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 1,258 days

from September 19, 2006, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 14th day of September 2006.



Jon W. Dudas

Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office